WO 2004/092035

Blister pack

The invention relates to a blister pack for pharmaceutical products, diagnostic products or medical devices, comprising a blister base part thermoformed from plastics material, a cover film made of aluminium or an aluminium/plastics material composite and a lower sealing tray, which is sealed against the rear of the blister base part and cold-formed from an aluminium/plastics material composite film.

In blister packs with a thermoformed blister base part known under the term "tropical blisters", the cover film consists of aluminium or an aluminium/plastics material composite, and a lower sealing tray, which is cold-formed from an aluminium/plastics material laminate, is sealed against the rear of the blister base part. Therefore, in a tropical blister, the blister base part with the filling is completely protected by the aluminium films in the cover layer and in the lower sealing tray against the penetration of steam and gases from the external atmosphere.

In the tropical blisters known today, the lower sealing tray is firmly sealed against the base part. The filling is pressed through the cover film by pressure on the aluminium/plastics material laminate and the thermoformed cup of the base part located below it. As neither the filling nor the individual cup is visible from outside, there may be problems in pressing out the filling.

No perforations may be provided in the case of cover films, which can be removed by peeling, because of the transverse diffusion of moisture and oxygen and the risk of the cover film tearing off. There is therefore a very high risk that not only the cup provided for opening is exposed when peeling the cover film, but the adjacent cup is also at least partially opened.

As the aluminium/plastics material laminate of the lower sealing tray ensures adequate protection of the filling against moisture, UV radiation and oxygen during

the logistics chain, PVC or PVC/40 to 60 g/m^2 PVDC is used as the plastics material for the thermoformed blister. So the guaranteed minimum durability of the filling is not exceeded, the blister pack has to be used up in a relatively short time once the filling has been removed for the first time.

The invention is based on the object of providing a tropical blister of the type mentioned at the outset, in which the filling is visible prior to removal and therefore can be pressed through the cover film without damaging adjacent regions. In addition, the durability of the filling is to be ensured for longer for the remaining pack after the first removal of filling, as a function of the plastics material used for the thermoformed base part.

The fact that the aluminium/plastics material composite film of the lower sealing tray has, on the side directed toward the blister base part, a peelable heat-sealing layer made of a lacquer with an application weight of 2 to 20 g/m^2, preferably 7 to 15 g/m^2, a peelable plastics material film with a film thickness of 10 to 40 µm, preferably 15 to 30 µm, or a peelable plastics material coating with an application weight of 5 to 40 g/m^2, preferably 7 to 20 g/m^2, leads to the achievement of the object.

Obviously, the solution according to the invention may also be used for the currently used thermoformed plastics materials for the "lower sealing tray".

To achieve an optimum durability of the filling, the plastics material of the blister base part has a barrier with a penetration barrier effect against steam and/or gases.

The plastics material of the blister base part with barrier properties may be constructed from a laminate with the layer sequence PVC/PVDC, PVC/PE/PVDC, PVC/PCTFE, PVC/PE/PCTFE, PVC/PCTFE/PVC. PVC/PE, PVC/COC/PE, PVC/COC/PVC, PVC/COC/PVDC, PVC/COC/PP, PVC/COC/PE. PVC/COC, PP/PVDC, PP/PCTFE, PP/PCTFE/PP, PP/COC/PP, PP/PET, PP/PE, PP/COC/PE, PP/COC/PCTFE, PP/COC, PET/PP/PVDC, PET/COC/PP,

PET/COC/PVC, PET/COC/PVDC, PET/COC/PE, PET/PVC/PCTFE, PET/COC, PE/PCTFE, HDPE/PVDC, HDPE/PVC, PE/PCTFE/PE, PE/COC/PVDC, PE/COC. The blister base part may also, however, consist of LCP, HDPE, PP, PVC or PET containing LCP.

The blister base part may also be constructed from the generally used plastics materials without special barrier properties, if the limited durability of the filling after removal of the lower sealing tray is taken into account.

In the blister pack according to the invention, a press-through film is preferred as a cover film. However, if a peelable opening is desired, the proposed solutions can obviously also be used.

The peelable heat-sealing layer which is directed toward the rear of the blister base part, of the aluminium/plastics material composite film of the lower sealing tray, is expediently constructed with the same chemical base components as the plastics material of the blister base part forming the sealing face, or mixtures of these base components with materials, which bring about an adhesive or cohesive break.

Materials which bring about an adhesive or cohesive break are, for example, acrylates, polybutylates, Morprime, styrene acrylate with polyolefin groups, PVC/AC plus acrylate, PP/butadiene or polyester/butadiene/styrene.

The peelable plastics material film which is directed toward the rear of the blister base part or the peelable plastics material coating which is directed toward the rear of the blister base part is preferably constructed on the basis of PVC, PP, metallocene PP, PE, metallocene PE, ACLAR® (PCTFE), PET, EAA, ionomers of PE and PE acrylates, EVA and copolymers with EVA.

The peelable plastics material film can be extruded, coextruded or lacquer-laminated with a peelable coating, and the plastics material coating can be coextruded with a peelable layer.

Further advantages, features and details of the invention emerge from the following description of preferred embodiments and with the aid of the drawings, in which, schematically:

Fig. 1 shows a cross-section through a part of a blister pack with a peelable lower sealing tray and a tear flap;

Fig. 2 shows a view of the blister pack of Fig. 1 with a first embodiment of a tear flap in the viewing direction A;

Fig. 3 shows a view of the blister pack of Fig. 1 with a second embodiment of a tear flap in the viewing direction A;

Fig. 4 shows a view of the blister pack of Fig. 1 with a third embodiment of a tear flap in the viewing direction A.

A blister pack 10 shown in Fig. 1 to 4 in the form of a tropical blister has a base part 12 with individual blisters or cups 14 formed therefrom to receive a pharmaceutical filling, not shown in the drawing, such as tablets or capsules, diagnostic products or medical devices, for example. On the side of the openings of the cups 14 a cover film 16 tightly sealing the cups 14 is sealed against the base part 12.

On the side opposing the cover film 16, a further film in the form of a lower sealing tray 18 extends over the formed cups 14 and is sealed against a peripheral edge 20 of the base part 12 so as to be peelable. The barrier properties of the lower sealing tray 18 prevent penetration of steam and gases from the external atmosphere into the filling space of the cups 14.

In the region of a side edge of the blister pack 10, the lower sealing tray is not sealed against the base part 12 in a narrow region 20a, forming a tear flap 22. Figs. 2 to 4 show different embodiments of tear flaps 22 or corresponding

unsealed zones. In an exemplary side edge length e of the blister pack 10 of 68 mm, the tear flap of Fig. 2 has a uniform width b of 7 mm. The tear flap of Fig. 3 has a width b_m of for example 2 mm in the middle and a width b_a of 7 mm on the outside. In the tear flap of Fig. 4, the width b_m is 7 mm in the middle, and the width b_a is 2 mm on the outer edge.

In the Table below, examples are compiled of aluminium/plastics material laminates used according to the invention as the material to produce the cold-formed lower sealing tray. The coating/lacquering of the aluminium film which is directed to the outside is designated "outside coating" and the coating/lacquering which is directed toward the plastics material on the outside of the blister base part for sealing is designated "inside coating", in each case giving the grams per square metre in coating/lacquering or the film thickness in lamination of the plastics material film. The table also contains the plastics materials selected in accordance with the inside coating/lacquering of the laminates of the lower sealing tray for the outside of the blister base part, against which the sealing of the aluminium/plastics material laminate is carried out.

Example	Outside coating	Al film	Inside coating	Outside base part
1	oPA, 25 µm	45 µm	HSL (hot-sealing lacquer) based on PVC/AC plus acrylate, 10 g/m^2	PVDC or PVC
2	oPA, 25 µm	60 µm		
3	oPP, 20 µm	45 µm		
4	PET film, 23 µm	45 µm		
5	oPA, 25 µm	45 µm	HSL based on acrylate with polyolefin groups, 10 g/m^2	
6	oPA, 25 µm	45 µm	PVC film, 10 µm, peelable	
7	oPA, 25 µm	45 µm	PVC film 15 µm, peelable	
8	oPA, 25 µm	45 µm	HSL based on PP/butadiene, 10 g/m^2	PP
9	oPA, 25 µm	60 µm		
10	oPP, 20 µm	45 µm		
11	PET film, 23 µm	45 µm		
12	oPA, 25 µm	45 µm	HSL based on acrylate with polyolefin groups, 10 g/m^2	
13	oPA, 25 µm	45 µm	PP film, 20 µm, peelable	
14	oPA, 25 µm	45 µm	HSL based on PVC/AC plus acrylate, 10 g/m^2	PET
15	oPA, 25 µm	60 µm		
16	oPP, 20 µm	45 µm		
17	PET film, 23 µm	45 µm		
18	oPA, 25 µm	45 µm	HSL based on polyester with acrylate, 10 g/m^2	
19	oPA, 25 µm	40 µm	HSL based on PVC/AC plus acrylate, 10 g/m^2	
20	oPA, 25 µm	45 µm	PET film, 12 µm, peelable	

Example	Outside coating	Al film	Inside coating	Outside base part
21	oPA, 25 µm	45 µm	HSL based on polyester/butadiene/styrene, 10 g/m^2	PE
22	oPA, 25 µm	60 µm		
23	oPA, 25 µm	40 µm		
24	oPA, 25 µm	36 µm		
25	oPP, 20 µm	45 µm		
26	PET film, 23 µm	45 µm		
27	oPA, 25 µm	45 µm	HSL based on acrylate with polyolefine groups, 10 g/m^2	
28	oPA, 25 µm	45 µm	PE peel film, 40 µm	
29	oPA, 25 µm	40 µm	HSL based on PVC/AC plus acrylate, 10 g/m^2	
30	oPA, 25 µm	36 µm		
31	oPA, 25 µm	40 µm	HSL based on PP/butadiene, 10 g/m^2	
32	oPA, 25 µm	36 µm		
33	oPA, 25 µm	36 µm	HSL based on PVC/AC plus acrylate, 10 g/m^2	
34	oPA, 25 µm	45 µm	HSL based on EVA/acrylate, 10 g/m^2	ACLAR® (PCTFE)
35	oPA, 25 µm	60 µm		
36	oPA, 25 µm	40 µm		
37	oPA, 25 µm	36 µm		
38	oPP, 20 µm	45 µm		
39	PET film, 23 µm	45 µm		
40	oPA, 25 µm	45 µm	HSL based on ACLAR®/EVA/acrylate	
41	oPA, 25 µm	45 µm	HSL based on EVA/copolymer, 20 g/m^2	